

U.S. Patent Application Serial No. 10/541,746  
Amendment filed April 24, 2008  
Reply to OA dated January 28, 2008

### **REMARKS**

Claims 1-36 are pending in this application. Claims 1-3, 5, 7, 19 and 20 are amended herein. Upon entry of this amendment, claims 1-36 will be pending. Entry of this amendment and reconsideration of the rejections are respectfully requested.

No new matter has been introduced by this Amendment. Support for the amendments to the claims is detailed below.

**Claim 20 is rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.** (Office action p. 2)

The Examiner states that there is no antecedent basis for "the silicone compound (C) and the N-substituted acrylamide (D) in the mixed solution."

The rejection is overcome by the amendment to claim 20, which clarifies that in the step of obtaining a mixed solution (with antecedent in claim 19), the mixed solution further comprises components (C) and (D).

**Claims 1-2, and 9-18 are rejected under 35 U.S.C. §102(b) as being anticipated by Baba et al. (WO 01/171415). For the purpose of examination, Baba et al. (U.S. Patent No. 6,638,991) was used as the English translation of Baba et al. (WO 01/171415).** (Office action p. 2)

The rejection of claims 1-2 and 9-18 is respectfully traversed. Reconsideration of the

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rejection is requested in view of the clarifying amendments to claims 1, 2, 3, 5, 7 and 19.

The Examiner cites Baba '991 at column 2, line 60, to column 4, line 45, as disclosing compound (A), and column 4, line 18, and column 9, lines 58-63, as disclosing pyrrolidone derivative (B), in an ocular lens material.

Applicant believes that the Examiner may have misunderstood the scope of the present claims, and the amendments to claims 1, 2, 3, 5, 7 and 19 clarify the chemical nomenclature in these claims. Specifically, the term "methylene group" has been changed to the more correct --vinylidene group--, that is, a group based on the radical  $\text{:C=CH}_2$ . This is the more proper nomenclature for the polymerizable group found, for example, in one of the methylene-pyrrolidones recited in the dependent claims. To clarify that the claim is reciting a methylene-pyrrolidone structure, the claims have been amended to recite: "a polymerizable group is a ~~methylen~~ vinylidene group that includes a carbon atom of a pyrrolidone ring."

Applicant submits that this amendment is a clarifying amendment only, and does not change the intended scope of the claims. The structure defined for compound (B) in the present application may be seen disclosure of the present application at page 1, line 16, and at page 16, line 14, to page 18, line 1.

The Examiner cites the monomer mixture in Baba '991 (column 4, line 18) and cites component (C-1), N-vinylpyrrolidone, as corresponding to component (B) of the present invention. However, **N-vinylpyrrolidone does not fall within the scope of compound (B) in the present claims.** The vinyl group in N-vinylpyrrolidone is on the Nitrogen, and not on the pyrrolidone ring.

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Applicant notes that the exemplary compounds for compound (B) in the present specification include for example, 1-methyl-3-methylene-2-pyrrolidone, and do not include N-vinylpyrrolidone.

The Examiner also cites column 9, lines 58-63, which disclose possible hydrophilic monomers (C-2), but these do not appear to include any methylene-pyrrolidones. There does not appear to be any suggestion in Baba et al. for a compound meeting the definition of compound (B) in the present claims.

**Claims 19, 21-26 are rejected under 35 U.S.C. §102(b) as being anticipated by Baba et al. (WO 01/171415). For the purpose of examination, Baba et al. (U.S. Patent No. 6,638,991) was used as the English translation of Baba et al. (WO 01/171415). (Office action p. 4)**

The rejection of claims 19 and 21-26 is respectfully traversed, and reconsideration is requested in view of the clarifying amendments to the claims.

As discussed above in regard to the rejection of claim 1, Baba et al. does not disclose or suggest a compound corresponding to compound (B) of the present claims. The definition of compound (B) is the same in claim 1 and claim 19.

**Claims 3-8 are rejected under 35 U.S.C. §103(a) as being unpatentable over Baba et al. (WO 01/171415) as applied to claim 1 above, and further in view of Shibata et al. (U.S. Patent No. 4,547,543). For the purpose of examination, Baba et al. (U.S. Patent No. 6,638,991) was used as the English translation of Baba et al. (WO 01/171415). (Office action p. 6)**

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The rejection of claims 3-8 is respectfully traversed, and reconsideration is requested.

The Examiner cites Baba as in the previous rejections, but states that Baba does not disclose 1-methyl-3-methylene-2-pyrrolidone "as the pyrrolidone derivative." The Examiner states that it would have been obvious:

"to have combined 1-methyl-3-methylene-2-pyrrolidone, as taught by Shibata et al. in the invention of Baba et al. and would have been motivated to do so since Shibata et al. suggests that such pyrrolidones provide good polymerizability with (meth)acryloyl groups, thereby decreasing poor optical and mechanical properties resulting from phase separation (1:40-62), and is an **equivalent alternative means** of providing a contact lens comprising pyrrolidone derivatives." (emphasis added)

Applicant notes that the Examiner refers to "combining" Baba et al. and Shibata et al., and to "combining 1-methyl-3-methylene-2-pyrrolidone ... in the invention of Baba et al.," but does not specifically state how this combination is to occur. In particular, the Examiner does not state if the 1-methyl-3-methylene-2-pyrrolidone is being **substituted** for a component in Baba et al., or is being **added** to the overall composition in Baba et al. The phrase "equivalent alternative means" appears to imply that this is a **substitution** for a pyrrolidone in Baba et al. However, it is not clear which component in Baba et al. is being referred to: component (C-1), which is N-vinylpyrrolidone, or the hydrophilic monomer (C-2). Applicant here addresses both the possible substitution of the 1-methyl-3-methylene-2-pyrrolidone (N-MMP) of Shibata for the N-vinylpyrrolidone of Baba, and the addition of N-MMP as an auxiliary component in Baba.

In traversing the rejection, Applicant first argues that there is no disclosure in the Shibata reference that would suggest the substitution of Shibata's 1-methyl-3-methylene-2-pyrrolidone (N-MMP) for the N-vinylpyrrolidone (N-VP) of Baba, or the addition of N-MMP to Baba's system.

Shibata's reasons for using N-MMP can be inferred from Shibata's disclosure, as follows. Shibata et al. discloses that N-MMP has "superior polymerizability and equal or superior hydrophilic nature as compared with N-VP" (column 1, line 64). The reference also discloses that "no substantial elution of a non-cross-linked N-MMP polymer is observed" (column 4, line 64).

Particularly noteworthy is the disclosure at column 2, line 25, that: "N-MMP ... is ... highly copolymerizable when copolymerized **with the alkyl acrylate or methacrylate** used as the reinforcing monomer units." Applicant notes in this regard that there is **no disclosure in the reference of copolymerization with silicone compounds**.

The reference discloses use of N-MMP in combination with N-VP at column 2, line 46. However, this is stated to be "to improve the hardness of the polymer and the consequential dimensional stability of the contact lens."

Shibata generally discloses as a goal **a hydrogel which "has a water content as high as from about 55 to about 90% by weight"** (column 4, line 60). That is, Shibata uses the N-MMP as **an auxiliary component** to N-VP to add a high copolymerizability with **the alkyl acrylate or methacrylate monomers**.

That is, the reasons for use of N-MMP in Shibata are **specifically for enhancement of N-VP and acrylate/methacrylate copolymerization**. There is no general suggestion in Shibata to substitute N-MMP for N-VP. With regard to addition as an auxiliary component, there is no suggestion in Shibata that N-MMP would have a beneficial effect on **systems using polysiloxane macromonomers**, such as Baba's system, which is based on polysiloxane macromonomer (A).

Applicant therefore submits that there is no suggestion or motivation in the references for the modification proposed by the Examiner, and that there is no *prima facie* case of obviousness over combination of Shibata and Baba.

In addition to the above argument attacking the *prima facie* case of obviousness, Applicant further submits that there are clearly unexpected results associated with the compositional limitations of the present claims.

Specifically, in Baba, which describes a silicone hydrogel lens made using N-VP, it is described that the lens, which has superior surface wettability and kinetic property, is obtained by exactly controlling the monomer and weight of crosslinking agent (see, for example, column 4, lines 34-44).

Note, in particular, the disclosure that:

“On the other hand, **when N-vinylpyrrolidone (C-1) is not used**, desirable low frictional property, lubricity and strain resistance cannot be imparted to the ocular lens material. From these fact, **it is essential to use N-vinylpyrrolidone (C-1) and the hydrophilic monomer (C-2) together**, and the polymerizable group in the hydrophilic monomer (C-2) is acryloyl group or allyl group in consideration of

copolymerizability with N-vinylpyrrolidone (C-1).” (column 9, lines 34-42, emphasis added)

That is, the disclosure of Baba is specific about the use of N-VP, and, in fact, this teaches away from replacement of the N-VP in the reference.

This disclosure also means that the effects of the present claims, in which there is a polydimethylsiloxane structure through a urethane bond **and** a pyrrolidone derivative in which a polymerizable group is a vinylidene group that includes a carbon atom of a pyrrolidone ring, are **completely unexpected** over Baba. It is described in the present specification that using N-MMP as an alternative compound to N-VP can decrease the residual monomer drastically, while maintaining properties such as superior hydrophilic property and wettability for the purpose of making silicone hydrogel lens (see Table 1-3, Example 1, Table 6-7, 11-12, Example 17, and Comparative Example 2, etc.).

For example, as shown in Table 4 of the present specification, the non-crosslinking polymer is eluted in the series of “silicone + N-VP” even after the elution treatment by water, but the quantity of elution becomes drastically reduced by using N-MMP. The effect of this is to simplify the step of elution treatment to decrease the residual monomer, to reduce the quantity of polymer elution after the sterilization, and therefore to obtain a contact lens which is highly safe.

This effect, commensurate with the claims of the present invention, is clearly not suggested by Baba or Shibata.

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Accordingly, claims 3-8 are not obvious over Baba et al. and Shibata et al., taken separately or in combination.

**Claim 27 is rejected under 35 U.S.C. §103(a) as being unpatentable over Baba et al. (WO 01/171415) as applied to claims 19 and 26 above, and further in view of Valiant, Jr. et al. (U.S. Publication No. 2002/0102415). For the purpose of examination, Baba et al. (U.S. Patent No. 6,638,991) was used as the English translation of Baba et al. (WO 01/171415). (Office action p. 7)**

**Claim 28 is rejected under 35 U.S.C. §103(a) as being unpatentable over Baba et al. (WO 01/171415) as applied to claims 19 and 26 above, and further in view of Hayashi et al. (U.S. Patent No. 6,503,632). For the purpose of examination, Baba et al. (U.S. Patent No. 6,638,991) was used as the English translation of Baba et al. (WO 01/171415). (Office action p. 8)**

**Claims 29-30 are rejected under 35 U.S.C. §103(a) as being unpatentable over Baba et al. (WO 01/171415) as applied to claims 19 and 26 above, and further in view of Walther et al. (U.S. Patent No. 6,379,004). For the purpose of examination, Baba et al. (U.S. Patent No. 6,638,991) was used as the English translation of Baba et al. (WO 01/171415). (Office action p. 8-9)**



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**Claims 31-35 are rejected under 35 U.S.C. §103(a) as being unpatentable over Baba et al. (WO 01/171415) as applied to claims 19 and 26 above, and further in view of Turek et al. (U.S. Publication No. 2002/0137811). For the purpose of examination, Baba et al. (U.S. Patent No. 6,638,991) was used as the English translation of Baba et al. (WO 01/171415). (Office action p. 9)**

**Claim 36 is rejected under 35 U.S.C. §103(a) as being unpatentable over Baba et al. (WO 01/171415) as applied to claim 19 above, and further in view of Niwa et al. (U.S. Patent No. 5,516,467). For the purpose of examination, Baba et al. (U.S. Patent No. 6,638,991) was used as the English translation of Baba et al. (WO 01/171415). (Office action p. 8-9)**

The rejections of claims 27-36 are respectfully traversed, and reconsideration of these rejections is requested.

Applicant has argued above in response to the rejection of base claim 19 over Baba et al., that Baba et al. does not teach, suggest or motivate the use compound (B) as recited in claim 19. The other references cited in these rejections--Valiant, Jr., Hayashi et al., Walther et al., Turek et al., and Niwa et al., also do not teach or suggest compound (B), and claims 27-36 are not obvious over these references, taken separately or in combination.

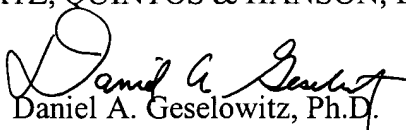
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If, for any reason, it is felt that this application is not now in condition for allowance, the Examiner is requested to contact the applicants' undersigned agent at the telephone number indicated below to arrange for an interview to expedite the disposition of this case.

In the event that this paper is not timely filed, the applicants respectfully petition for an appropriate extension of time. Please charge any fees for such an extension of time and any other fees which may be due with respect to this paper, to Deposit Account No. 01-2340.

Respectfully submitted,

KRATZ, QUINTOS & HANSON, LLP

  
Daniel A. Geselowitz, Ph.D.  
Agent for Applicants  
Reg. No. 42,573

DAG/xl

Atty. Docket No. **050443**  
Suite 400  
1420 K Street, N.W.  
Washington, D.C. 20005  
(202) 659-2930



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